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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/527,376 | 03/16/2000 | Ralf M. Luche | 200125.407 | 2363 |

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/24/2003

UD

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/527,376 | LUCHE ET AL. | |
| | Examiner | Art Unit | |
| | Elizabeth Slobodyansky | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-50 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 46 and 47, drawn to a polypeptide of SEQ ID NO: 2 and a mutant thereof, classified in class 435, subclass 196.
- II. Claims 1-14, drawn to a DNA encoding SEQ ID NO:2, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.
- III. Claims 15-21, drawn to an antibody against a polypeptide of SEQ ID NO:2, methods of use thereof and pharmaceutical compositions comprising thereof, classified in class 424, subclass 146.1.
- IV. Claims 22-25 drawn to hybridization methods, classified in class 435, subclass 6.
- V. Claims 26-29 and 48-50, drawn to methods of screening for agents that modulate DSP-2 activity, classified in class 435, subclass 19.
- VI. Claims 30-32, drawn to methods of screening for agents that modulate expression of DSP-2, classified in class 435, subclass 6.

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VII. Claims 33-41, drawn to *in vitro* methods of use of an agent, classified tentatively in class 435, subclass 375.

VIII. Claims 42-45, drawn to methods of treating a patient with an agent, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are patentably distinct because an enzyme, a DNA and an agent are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of invention II are not limited in use for the production of a polypeptide of invention I and can be used as hybridization probes in invention IV, and a polypeptide of invention I can be obtained by a materially different method such as by the biochemical purification or chemical synthesis. While a polypeptide of invention I is related to an antibody of invention III as being cognate antigen, the structure of an antibody is unpredictable from the structure of the polypeptide of invention I. An agent used in inventions VII and VIII can be used in each of these inventions as well as for modulation activities of other biomolecules and for the production of antibodies.

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Inventions (I and V) and (II and IV), respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a polypeptide of invention I can be used in a method of invention V and for the production of antibodies. A DNA of invention II can be used in the production of a polypeptide of invention I and as a hybridization probe.

Methods of inventions IV-VIII are patentably distinct as drawn to materially different methods employing different products such as a DNA, a polypeptide and an agent.

Methods of inventions IV and VI are using DNAs of different structures and functions, such as a structural DNA and a promoter.

Inventions VII and VIII are patentably distinct because they are directed to materially different *in vitro* and *in vivo* methods employing different protocols and routes of administration of an agent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

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A telephone call was made to Dr. Stephen Rosenman on April 14, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner